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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/319,541 | 08/19/99 | MULLER | R 62-659-50781 |

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| ART UNIT | PAPER NUMBER |
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020736
FARKAS & MANELLI
2000 M STREET NW SUITE 700
WASHINGTON DC 20036-3307

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/319,541 | Muller et al |
| **Examiner** | **Group Art Unit** |
| Shahnam Sharareh | 1616 |

☒ Responsive to communication(s) filed on *Aug 19, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

☒ Claim(s) *1-18* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

***--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---***

## DETAILED ACTION

The Preliminary Amendment filed on June 8, 1999 has been entered. Accordingly, claims 1-18 have been amended. Claims 1-18 are now pending.

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3, 7-8, 10, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "and/or" in the instant claims are confusing. For example, in claim 1, it is not clear whether the instant composition comprising a polymeric matrix, an excipient phase and an active substance, or a polymeric matrix, an excipient phase or an active substance. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

4. Claim 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. The instant claim recites the phrase " (bleached wax, German Pharmacopeia, 9th edition.)", the limitations of which is not clear and precise. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation lipid peptides, and the claim also recites "in particular synthetic..." or "specifically hydrogenated fat ..." which is the narrower statement of the range/limitation.

5. Claim 13-14, 16 recites the limitation "this suspension". There is insufficient antecedent basis for this limitation in the claim.

6. Claim 17-18 provide for the use of formulation in the form of a matrix material, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1-11, 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by McClelland et al WO 94/00111.

The instant claims are directed to compositions comprising a polymeric matrix, an excipient phase, and an active substance phase, wherein the content of the polymeric matrix material phase comprise polyacrylates and form 40-70% of the formulation. The instant claims

are directed to methods of preparing said compositions comprising suspending or dissolving the phases in a liquid and then spray drying the resulting suspension.

McClelland et al disclose methods of preparing spherical micro particles comprising mixing a polymeric entity such as Amberlite IRP-276 (TM) with a suitable excipient such as citric acid in a granulating solution and then extruding the resulting suspension to yield micro particles and finally spray drying them (see example 1, claims 1-9.) McClelland et al also disclose that their compositions can comprise 10%-70% by weight of the polymeric phase (see page 4 line 6 and example 3.) Thus, McClelland et al meet the limitations set forth in the instant claims.

Claim 1-3, 8-11, 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang US Patent 5,006,345.

The instant claims are directed to compositions comprising a polymeric matrix, an excipient phase, and an active substance phase, wherein the content of the polymeric matrix material phase comprise polyacrylates and form 1-98% of the formulation. The instant claims are directed to methods of preparing said compositions comprising suspending or dissolving the phases in a liquid and then spray drying the resulting suspension.

Lang disclose formulations comprising an excipient phase consisting of lactose, a polymeric phase, an active substance, and other suitable pharmaceutical excipients (see abstract, col 4 lines 1-42.) Lang also disclose various methods of preparing such his formulation comprising spray granulation, wet granulation, spray drying (see col 2 lines 58-67.) Thus, Lang meet the limitations set forth in the instant claims.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

10. Claims 1-12, 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Sparks et al US Patent 5,505,962.

The instant claims are directed to compositions comprising a polymeric matrix, an excipient phase, and an active substance phase, wherein the content of the polymeric matrix forms 40-70% of the formulation. The instant claims are directed to methods of preparing said compositions comprising direct compression or suspending or dissolving the phases in a liquid and then spray drying the resulting suspension.

Sparks et al disclose improved controlled release tablet formulations of potassium chloride comprising a polymeric matrix comprising acrylates or methacrylates (see col 4 lines 35-56), an excipient phase comprising lactose, talc, microcrystalline cellulose (col 4 lines 35-47, and col8 lines 58-60), and an active drug such as potassium chloride. Sparks et al disclose methods of preparing comprising wet granulation, direct compression into oval tablets (see col 6 lines 1-45, specifically lines 22-24.) The formulation of Sparks may further comprise a plasticizer and a surfactant (see col 5 lines 1-27.) Thus, Sparks et al meet the limitations set forth in the instant claims.

11. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Motta US Patent 5,662,935.

The instant claims are directed to compositions comprising a polymeric matrix comprising acrylic polymers and/or lipophilic moieties such as triglycerides, an excipient phase, and an active substance phase, wherein the content of the polymeric matrix forms 40-70% of the formulation. The instant claims are directed to methods of preparing said compositions comprising direct compression or suspending or dissolving the phases in a liquid and then spray drying the resulting suspension.

Motta disclose methods of preparing controlled release pharmaceutical forms comprising an active ingredient and one or more excipient which is compacted by direct compression, wherein said excipient comprise a polymeric entity such as acrylic polymers (see col 5 lines 3-21, example 1-2 claims 1-4.) The controlled release formulation of Motta may further comprise a filler agent such as lactose, as well as a triglyceride moiety to influence the hydrophilic/lipophilic properties of the composition (see claims 1, 5, 8, 17-18.) Thus, Motta meets the limitations set forth in the instant claim.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-18 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lang US Patent 5,006,345 in view of Motta US Patent 5,662,935.

The instant claims are directed to compositions comprising a polymeric matrix comprising polymers such as methacrylates and/or a lipid moiety such as triglycerides, an excipient phase, and an active substance phase, wherein the content of the polymeric matrix forms 40-70% of the formulation. The instant claims are directed to methods of preparing said compositions comprising direct compression or suspending or dissolving the phases in a liquid and then spray drying the resulting suspension.

The teachings of Lang and Motta have been discussed above. Although Lang does not disclose the use of various suitable polymers matrices as means for controlled drug delivery he teaches the use of such polymers as a binder to enhance the integrity of his compositions. Motto et al disclose that the controlled release properties of a dosage form may be increased if the concentration of its polymeric phase is increased to a range of 35-70%, therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to increase the polymeric concentration of Lang's dosage form to obtain a formulation that provides prolong therapeutic effect, because he would have had a reasonable expectation to succeed in formulating a controlled release polymeric dosage form by modifying the polymeric concentration of Lang's composition

as taught by Motto. Accordingly, process of preparing and using such formulations would have also been obvious.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Jose Dees can be reached on 703-308-4628. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjs 4/16/2000*

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616